UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF VIRGINIA
ABINGDON

UNITED STATES OF AMERICA	)	
	)	**Criminal No.**
v.	)	
	)	**Violations: 21 U.S.C. §§ 331(a),**
MIDWEST VETERINARY SUPPLY, INC.	)	**333(a)(1), and 352(f)(1)**

INFORMATION

INTRODUCTION

1. Defendant MIDWEST VETERINARY SUPPLY, INC. ("MIDWEST") is a Minnesota corporation with its principal place of business in Minnesota. MIDWEST dispenses, distributes and sells, among other products, veterinary prescription drugs to customers across the United States. Specifically, MIDWEST obtains prescription drugs for animals from manufacturers for further distribution to veterinarians, farms, feedlots, and others.

2. The Food and Drug Administration ("FDA") of the United States Department of Health and Human Services regulates the distribution and labeling of all drugs, including animal drugs, shipped or received in interstate commerce through enforcement of the Federal Food, Drug, and Cosmetic Act. 21 U.S.C § 301, *et seq.* ("FDCA"). Veterinary prescription drugs are drugs intended for use by animals that, because of their toxicity or other potentiality for harmful effect, or the method of their use, or the collateral measures necessary for their use, are not safe for animal use except under the professional supervision of a licensed veterinarian. 21 U.S.C. § 353(f)(1)(A).

3. Under the FDCA, a drug is misbranded if, among other things, its labeling does not bear "adequate directions for use." 21 U.S.C. § 352(f)(1). Adequate directions for use is defined as "directions under which the *layman* can use a drug safely and for the purposes for

which it is intended." 21 C.F.R. § 201.5 (emphasis added). Prescription veterinary drugs by definition can only safely be used under the professional supervision of a licensed veterinarian and therefore they must qualify for an exemption to this requirement in order to move in interstate commerce. These exemptions are set out in 21 C.F.R. Part 201, Subpart D ("Exemptions from Adequate Directions for Use").

4. Veterinary prescription drugs are exempt from the requirement that their labeling contain adequate directions for use if they meet all enumerated conditions, including that they be distributed through a closed supply chain in which every entity that possesses a prescription drug must have legal authorization to do so. *See* 21 C.F.R. § 201.105 (a)(1) (a veterinary prescription drug must be in the possession of: a person lawfully engaged in the manufacture, transportation, storage or wholesale distribution of drugs; a retail pharmacy or other person authorized under state law to dispense veterinary prescription drugs; or a licensed veterinarian for use in the course of his professional practice). Moreover, the veterinary prescription drug must be dispensed in accordance with 21 U.S.C. § 353(f), i.e., pursuant to a lawful order of a licensed veterinarian in the course of the veterinarian's professional practice. 21 U.S.C. § 353(f)(1) & 21 C.F.R. § 201.105 (a)(2). In other words, all veterinary prescription drugs must be dispensed (a) by a pharmacy pursuant to a valid prescription issued by a veterinarian or (b) dispensed directly by a veterinarian.

5. In certain states in the United States, veterinary prescription drugs may only be shipped to locations authorized by the state. Shipment of prescription drugs from a non-pharmacy to a non-authorized location is outside of the approved closed supply chain and, accordingly, such prescription drugs are not exempt from the requirement that their labeling

contain adequate directions for use. The shipments in question from MIDWEST failed to include adequate directions for use and accordingly, were misbranded.

6. The FDCA's restrictions on veterinary prescription drugs not only protect animals from the potential harms of prescription drugs, but are, in part, to prevent overuse of antibiotics and other prescription drugs which can lead to development of drug-resistant bacteria and microbes. Also, as to drugs used by animals that are in the human food supply, the restrictions protect the human food supply from unsafe drug residue in the edible tissues of animals sold for slaughter. Common causes of illegal residue include: (1) exceeding the drug's approved dose; (2) using a shorter withdrawal period than what is stated on the drug's label (if a higher than approved dose is given, the labeled withdrawal period may not be enough to allow the drug in the edible tissues to deplete to levels that are at or below the tolerance); (3) using a drug in an extra-label manner (for indications and dosages outside the approved labeling) without a veterinarian's involvement; (4) giving a drug not approved for that species; and (5) using an unapproved route of administration. Drug residue in the nation's food supply is concerning because: (1) they may contribute to antibiotic resistance in the human population, rendering human drugs less effective to treat human disease and contributing to the mutations of "superbugs"; and (2) they may cause allergic reactions in individuals with certain drug allergies.

7. From 2011 to 2021, MIDWEST caused misbranded veterinary prescription drug shipments to be made throughout the United States by distributing veterinary prescription drugs from its wholesale locations directly to end users in states where such shipments were illegal. MIDWEST obtained not less than $10,150,014 (ten million one hundred fifty thousand fourteen dollars) from such shipments. Its profits from such shipments were a small percentage of the amount received.

COUNT ONE

Introduction of Misbranded Drugs into Interstate Commerce
21 U.S.C. §§ 331(a), 333(a)(1), and 352(f)(1)

The United States Attorney charges that:

8. The Introduction is realleged and incorporated by reference into this Count.

9. From 2011 to 2021, in the Western District of Virginia, MIDWEST VETERINARY SUPPLY, INC. ("MIDWEST") introduced and delivered for introduction, and caused the introduction and delivery for introduction, into interstate commerce, of veterinary prescription drugs that were misbranded in that the drugs' labeling did not bear adequate directions for the use of such drugs.

10. The offense conduct included, but was not limited to, the following:

a. MIDWEST distributed veterinary prescription drugs directly from their non-pharmacy locations to various end-users; and

b. MIDWEST distributed veterinary prescription drugs to locations that were not authorized locations to which prescription drugs could legally be shipped.

11. Since these veterinary prescription drugs were not lawfully distributed, they failed to qualify for the exemption from the requirement that they bear labeling containing adequate directions for lay use. Accordingly, such shipments were shipments of misbranded drugs.

12. All in violation of Title 21, United States Code, Sections 331(a), 333(a)(1), and 352(f)(1).

NOTICE OF FORFEITURE

13. Upon conviction of the offense alleged in this Information, MIDWEST shall forfeit to the United States veterinary prescription drugs that were misbranded or became misbranded as a result of MIDWEST's conduct, pursuant to 21 U.S.C. § 334 and 28 U.S.C. § 2461.

14. Because the above-described forfeitable property has been transferred and sold to third parties and cannot be located upon the exercise of due diligence, the United States intends to seek forfeiture of $10,150,014 (ten million one hundred fifty thousand fourteen dollars); pursuant to 21 U.S.C. § 853(p).

DATED: March 22, 2023

Randy Ramseyer

for CHRISTOPHER R. KAVANAUGH
United States Attorney